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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/512,260	02/24/2000	Lynn M. Adams	03037.86702	5959

22907 7590 10/20/2003

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EXAMINER

DEBERRY, REGINA M

ART UNIT PAPER NUMBER

1647

DATE MAILED: 10/20/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/512,260

Applicant(s)

ADAMS ET AL.

Examiner

Regina M. DeBerry

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 8-34 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-7,35 and 36 is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Examiner's Amendment*.

19/D RMO
10/17/03

DETAILED ACTION

This application is in condition for allowance except for the following formal matters: The instant application fails to fully comply with the sequence rules 37 CFR 1.821-1.825 because each disclosure of a sequence embraced by the definitions set forth in the rules fails to refer to the required sequence identifier (SEQ ID NO:). This occurs in Figure 1A (NEG1 and NEG2). Sequences appearing in drawings may be referenced in the drawings themselves or in the corresponding Brief Description thereof.

Applicants must provide a CRF and a paper copy of the Sequence Listing, as well as an amendment directing its entry into the specification. Applicant must also submit a statement that the content of the paper and computer readable copies are the same and include no new matter. A complete response to this office action includes compliance with this sequence rule compliance.

Applicants are also required to cancel the non-elected claims.

Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

A shortened statutory period for reply to this action is set to expire TWO MONTHS from the mailing date of this letter.

EXAMINER'S AMENDMENT

An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this Examiner's amendment was given in a telephone interview with Michelle Homes-Son on 14 October 2003.

The application has been amended as follows:

- DI
1. An isolated polypeptide [comprising] consisting of a portion of CFTR (cystic fibrosis transmembrane conductance regulator) protein wherein said portion consists of between 18 and 100 amino acid residues, wherein said portion comprises 18 amino acid residues as shown in SEQ ID NO: 1.
 2. The polypeptide of claim 1 wherein the portion of CFTR protein comprises 22 amino acid residues as shown in SEQ ID NO: 2.
 3. The polypeptide of claim [1] 8 wherein the polypeptide is fused to a membrane-penetrating peptide.
-

4. The polypeptide of claim [2] 9 wherein the polypeptide is fused to a membrane-penetrating peptide.

5. The polypeptide of claim 3 wherein the membrane-penetrating peptide is selected from the group consisting of: VP-22 (SEQ ID NO: 3), (SEQ ID NO: 4), and (SEQ ID NO: 5).

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contd
6. The polypeptide of claim 4 wherein the membrane-penetrating peptide is selected from the group consisting of: VP-22 (SEQ ID NO: 3), (SEQ ID NO: 4), and (SEQ ID NO: 5).

7. The polypeptide of claim 1, wherein the portion of CFTR protein consists of a sequence of amino acid residues as shown in SEQ ID NO: 2, and wherein the portion is free of phosphorylation.

D2
35. An isolated fusion protein consisting of: a portion of CFTR protein wherein said portion consists of between 18 and 100 amino acid residues, and wherein said portion comprises 18 amino acid residues as shown in SEQ ID NO:1; and a polypeptide which provides an additional functional property.

36. The isolated fusion protein of claim 8 wherein the portion of CFTR protein comprises 22 amino acid residues as shown in SEQ ID NO:2.

Matter of Record

Applicants have added new claims 8 and 9. The instant claims have been renumbered "35" and "36" under Rule 37 CFR 1.126.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on 9:00 a.m.-6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



RMD
October 17, 2003



YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600